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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,476	07/03/2001	Edoardo Camenzind	017753-148	2491

7590 01/02/2003

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,476

Applicant(s)

CAMENZIND ET AL.

Examiner

Anu Ramana

Art Unit

3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 17 October 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on 10/11/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the inflatable chamber" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barath (US 5,616,419) in view of Lin et al. (US 5,792,105).

Barath discloses a balloon catheter 2 with sharp longitudinal processes or cutting edges 6 that protrude parallel with the longitudinal axis of the surface of the balloon (Figure 1, col. 3, lines 63-67 and col. 4, lines 1-30) such that when balloon 2 is inflated, the cutting edges penetrate the vessel wall (7,8) to make longitudinal cuts (Figure 3). Barath further discloses a device with the cutting means 6 within the lumen of a conventional balloon catheter 28 (Figures 24-27) such that after making longitudinal cuts in the vessel wall, the balloon catheter 28 is moved into place and inflated to dilate the vessel (col. 6, lines 21-30).

Barath does not disclose that balloon catheter 28 is a medication-dispensing catheter.

Art Unit: 3751

Medication dispensing catheters to dispense medication to a cross section of an artery that has been forcibly expanded are well known. Lin et al. teach a medication dispensing catheter with a balloon 10 having an inner balloon wall and channels 16 spaced circumferentially around balloon 10 wherein each channel terminates in an outlet 20 on the outer balloon wall 14 through which medication is delivered (Figure 1 and col. 3, lines 21-30).

Accordingly it would have been well known to one of ordinary skill in the art at the time of the invention to have replaced balloon catheter 28 in the Barath device with a medication dispensing catheter, as taught by Lin et al., to deliver medication to the vessel wall.

Regarding claim 14, the functional statement of intended use has been carefully considered but is deemed not to impose any structure on the claim distinguishable over the Barath-Lin apparatus.

Regarding claim 18, Lin et al. teach an inflatable dispenser. It would have been a matter of obvious design choice to have utilized a cuff or "inflatable band" since the applicant has not disclosed that a cuff solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a balloon.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barath (US 5,616,419) in view of Lin et al. (US 5,792,105), further in view of Lemelson et al. (US 5,728,123).

See discussion for claim 2.

Lemelson et al. teach a catheter 9 having a radially expandable balloon or "inflatable chamber" 11 secured around its distal end with blade support arms 16 having cutting blades 18 whereby expansion of balloon 11 forces the blade support arms 16 radially outward to operatively extend the cutting blades 18 (col. 3, lines 38-45; col. 4, lines 1-4 and lines 12-14; Figure 1A; and Figure 1B). Lemelson et al. also teach that catheter 9 overcomes the problems associated with a typical artherectomy catheter where the cutting blades extend to the desired cutting radius while the artherectomy catheter is being maneuvered to the correct position ("treatment site") resulting in the risk of inadvertent injury as well as an encumbered passage of the artherectomy catheter (col. 2, lines 37-42). Further, Lemelson et al. also teach an embodiment (Figure 2A/2B) wherein the blade support arms 27 are attached to a tube 20

Art Unit: 3751

carrying a balloon 22 by a tube 25 which extends from tube 20 into the balloon or "inflatable chamber" 22 (col. 4, lines 24-32).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a catheter 9 as taught by Lemelson in the Barath-Lin apparatus wherein the cutting blades extend to the desired cutting radius, to provide for operative extension of cutting blades 14 to allow for unencumbered passage of the cutting or entry means of the Barath-Lin apparatus to the treatment site with avoidance of inadvertent injury.

Conclusion

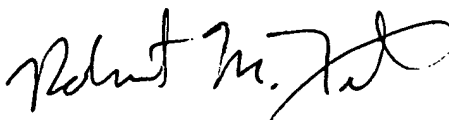
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached at (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR
December 27, 2002



**ROBERT M. FETSUGA
PRIMARY EXAMINER**